

REMARKS

I. CLAIM STATUS

Claims 1-26 are pending. No claims are amended herein.

Applicants acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. § 112 and the rejection under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,577,796 and WO 00/21098 in view of Uemura et al.

II. REJECTIONS UNDER 35 U.S.C. § 103(a)

The Examiner rejects claims 1-26 under 35 U.S.C. § 103 as unpatentable over Anelli et al. (U.S. Patent No. 6,577,796 and WO 00/21098) in view of Uemura et al. (U.S. Patent No. 5,134,036) and Kamachi et al. (U.S. Patent No. 5,187,226). *See* Jan. 25, 2008, Office Action at 2-4. The Examiner reiterates the same rationale for relying upon Anelli and Uemura as stated in the previous office action, but now also relies upon Kamachi. In particular, the Examiner asserts that "Kamachi discloses vinyl alcohol polymers and copolymers with vinyl acetate that are produced by a process that includes hydrolysis in the presence of an antioxidant such as 'IRGANOX 1098' which enhances the degree of polymerization in the presence of oxygen." *Id.* at 3. The Examiner concludes that it would have been obvious "to modify the teachings of Anelli wherein the partial hydrolysis of his copolymer is performed in the presence of an antioxidant such as 'IRGANOX 1098', . . . in order to enhance the degree of polymerization of the instant claimed copolymer." *Id.* at 4.

Applicants respectfully disagree and traverse this rejection for the reasons of record and for at least the following reasons.

Several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or nonobviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. 467; *see also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1730, 82 U.S.P.Q.2d 1385, 1388 (2007).

Indeed, to establish a *prima facie* case of obviousness, the Examiner must:

make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

M.P.E.P. § 2142. “The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” *Id.* It is important to note, moreover, that the prior art references relied upon in a rejection “must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” when such reasons are articulated by

the Examiner. M.P.E.P. § 2141.03(VI) (second emphasis added); *see also Graham*, 383 U.S. at 17, 148 U.S.P.Q. 467.

Applicants respectfully submit that the Examiner has still not established a *prima facie* case of obviousness because there would have been no motivation to incorporate the antioxidants of Uemura or Kamachi for the stabilizers of Anelli and no reasonable expectation of success to arrive at Applicants' claimed invention, when Uemura, Kamachi, and Anelli are considered **as a whole**.

Initially, Applicants note that the Examiner has essentially agreed with Applicants that the antioxidants of Uemura are not interchangeable with the stabilizers of Anelli. *See* Jan. 25, 2008, Office Action at 3. Indeed, the Examiner tacitly recognizes this point by stating that "Uemura discloses ethylene-vinyl alcohol copolymers produced by saponification of ethylene-vinyl ester (such as vinyl acetate) in the presence of an antioxidant" *See id.* (emphasis added). Similarly, the Examiner states that "Kamachi discloses vinyl alcohol polymers and copolymers with vinyl acetate that are produced by a process that includes hydrolysis [i.e., saponification] in the presence of an antioxidant. . . . " *Id.* (emphasis added). In other words, the antioxidants of Uemura and Kamachi are understood to serve a function during the manufacturing process of the copolymer.

In contrast, Anelli discloses a product comprising a different copolymer, a vinyl alcohol/vinyl acetate copolymer, wherein stabilizers may be added in a sufficient amount to the already saponified copolymer to form its inventive product. *See* Anelli, page 10, lines 20-27 and page 18, lines 1-8. In other words, the stabilizers of Anelli serve their function after the vinyl alcohol/vinyl acetate copolymer product has been

manufactured. Applicants submit that given these differences, there is no expectation of interchangeability and, thus, no motivation to combine the antioxidants of Uemura with the composition of Anelli and no reasonable expectation of success.

Moreover, the cited prior art does not offer one skilled in the art a motivation to use the claimed hydrolysis stabilizer to stabilize an already produced vinyl alcohol/vinyl acetate copolymer. Rather, the cited prior art only teaches that the claimed stabilizers are only known to be effective for alternative purposes, and the cited prior art does not provide any direction/motivation to select the very narrow set of claimed stabilizers.

Specifically, Uemura and Kamachi disclose using stabilizers to produce a copolymer. As the Examiner recognizes, "Uemura discloses ethylene-vinyl alcohol copolymers produced by saponification of ethylene-vinyl ester (such as vinyl acetate) in the presence of an antioxidant" Jan. 25, 2008, Office Action at 3 (emphasis added). Finally, Kamachi discloses that "[i]n the substantial absence of oxygen or in the presence of an antioxidant, the vinyl alcohol polymer . . . can be produced . . . by the hydrolysis of the homopolymer of copolymer of a vinyl ester" Kamachi, col. 4, lines 39-47 (emphasis added).

In contrast, the present invention concerns the problem of stabilizing (i.e., preventing further saponification/hydrolysis) of a water-soluble polymeric composition comprising a vinyl alcohol/vinyl acetate copolymer and a plasticizer, and provides the solution by means of a hydrolysis stabilizer having specific molecular characteristics and added in a specific amount. The present invention does not concern itself with the production of a vinyl alcohol/vinyl acetate copolymer. Thus, one skilled in the art reading Uemura or Kamachi would not have been motivated to use a hydrolysis

stabilizer, as-claimed, in Anelli in order to stabilize an already produced vinyl alcohol/vinyl acetate copolymer. In particular, one skilled in the art would not be motivated to use a compound, which is disclosed to be necessary to hydrolyze/saponify the copolymer, as a stabilizer to prevent further hydrolyzation/saponification of that same copolymer.

Furthermore, it appears that the Examiner has not fully appreciated the unexpected results achieved by addition of a suitable amount of hydrolysis stabilizer having the claimed molecular characteristics. As discussed in Applicants' prior response, Applicants have discovered that compositions containing hydrolysis stabilizers within the scope of the claims (e.g., Irganox® 1098) have unexpectedly superior properties as compared to compositions containing stabilizers outside the scope of the claims (e.g., Irganox® 1010). Yet, both Uemura and Kamachi incorrectly deem those compounds to be equivalent antioxidants. To that extent, the addition of Kamachi to the rejection does not provide an additional or improved basis for arguing obviousness.

In particular, Uemura teaches the saponification of ethylene-vinyl alcohol copolymers and states that "[i]t is primarily important that the saponification be carried out in the absence of oxygen or in the presence of an antioxidant." Uemura, col. 3, lines 43-45 (emphasis added). Furthermore, "[t]he antioxidant is not particularly limited as long as it does not act adversely to the saponification reaction . . . and is representatively exemplified by, for example, hindered phenol antioxidants," such as Irganox® 1010 and Irganox® 1098. *Id.* at col. 3, line 50 – col. 4, line 13.

Likewise, Kamachi discloses producing the vinyl alcohol polymer by the hydrolysis of the homopolymer of copolymer of a vinyl ester, such as vinyl acetate, “[i]n the substantial absence of oxygen or in the presence of an antioxidant.” Kamachi, col. 3, lines 43-48, col. 4, lines 39-47. Like Uemura, Kamachi shows no preference for any particular antioxidant and merely notes that “[a]ny antioxidant may be used in the processes of the present invention insofar as it does not exert harmful influences upon the hydrolysis and does not lose its activity against the oxidation of the reaction system.” *Id.* at col. 6, lines 60-64. Kamachi lists both IRGANOX 1010 and IRGANOX 1098 as examples of such antioxidants. *See id.* at col. 6, line 65 – col. 7, line 24.

The present invention recites a water-soluble polymeric composition comprising, *inter alia*, “a hydrolysis stabilizer compound comprising a chelant group comprising two hydrogen atoms bonded to two respective heteroatoms selected from nitrogen, oxygen and sulphur, said two hydrogen atoms having a distance between each other of from 4.2×10^{-10} m to 5.8×10^{-10} m, said stabilizer compound being present in an amount of at least 0.75 mmoles per 100 g copolymer.” Claim 1 (emphasis added).

As Applicants noted previously, the distance between the hydrogen atoms of -NH- in Irganox® 1098 is 5.0×10^{-10} m, while the distance between the hydrogen atoms of -C(OH)- in Irganox® 1010 is 8.7 to 10.5×10^{-10} m, which is outside the recited range of claim 1. Table 2 of the present application shows the effectiveness of a hydrolysis stabilizer according to the invention (composition 1, containing Irganox® 1098) versus hydrolysis stabilizers having a hydrogen distance outside of the claimed range (e.g., composition 5, containing Irganox® 1010, which had the worst reported value). This experimental data unequivocally demonstrates that hydrolysis stabilizers within the

scope of the claims, such as Irganox® 1098, are unexpectedly superior to stabilizers that are outside the scope of the claims, such as Irganox® 1010 for the purpose of stabilizing an existing vinyl alcohol/vinyl acetate copolymer. Yet, Uemura, Kamachi, and the prior art do not appreciate these unexpectedly superior results, which the Examiner must consider in her determination of obviousness. *See* M.P.E.P. § 2141(V).

Regarding the claimed amount of the hydrolysis stabilizer, the Examiner argues that it would have been obvious to optimize the amount of the stabilizer because it is, presumably, a result-effective variable. *See* Jan. 25, 2008, Office Action at 4. This argument is inapplicable here where there is no evidence that the prior art appreciated the effects of varying the amount of hydrolysis stabilizer when used to stabilize an existing vinyl alcohol/vinyl acetate copolymer. *See Ex parte Beer*, Appeal No. 1996-0044, 1996 WL 1748764, at *2 (Bd. Pat. App. & Int. Apr. 15, 1999) (“The determination of a specific parameter can be an obvious expedient only when the art appreciates that said parameter is a result effective variable.”) (emphasis added); *see also* M.P.E.P. § 2144.05(II)(B) (“A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.”) (emphasis added).

Uemura says nothing about using a specific amount of antioxidant, and merely mentions that “[t]he antioxidant is not particularly limited as long as it does not act adversely to the saponification reaction and does not cause a loss of antioxidant action in the saponification system” Uemura, col. 3, lines 50-55. Kamachi merely mentions that “any antioxidant may be used . . . insofar as it does not exert harmful

influences upon the hydrolysis and does not lose its activity against the oxidation of the reaction system.” Kamachi, col. 6, lines 60-64. When an antioxidant is used, Kamachi states that “a smaller amount of the antioxidant can bring about the above-described effect if a part of oxygen in the system would be removed from the system by the aforementioned process.” Kamachi, col. 7, lines 30-34.

Not only do Uemura and Kamachi fail to recognize the amount of the hydrolysis stabilizer as a result-effective parameter when used in their hydrolysis/saponification processes to form vinyl alcohol/vinyl acetate copolymer, they also fail to recognize the amount of the hydrolysis stabilizer as a result-effective parameter when used in combination with an existing vinyl alcohol/vinyl acetate, as claimed, to prevent further hydrolyzation/saponification. Thus, it would not have been obvious to one of ordinary skill in the art to determine the optimum amount of the hydrolysis stabilizer through routine or manipulative experimentation in order to achieve the desired result.

In contrast, Applicants demonstrated how the claimed amount of the hydrolysis stabilizer limits the hydrolytic degradation of the already produced polymer material. For example, a first composition containing 0.5 phr Irganox® 1098 (0.78 mmoles per 100 g of VA-VAc copolymer) and a second composition containing 0.1 phr Irganox® 1098 (0.16 mmoles per 100 g of VA-VAc copolymer) were prepared. *See* Specification as-published (U.S. Patent Application Publication No. 2005/0175834 A1) at ¶ [0129]. At the end of an aging test, the saponification number for the first composition, which contained an amount of hydrolysis stabilizer as-claimed, was significantly better than that for the second composition, which contained an amount of

hydrolysis stabilizer outside the scope of the claims. *See id.* Nothing in Uemura and Kamachi suggest a recognition of this.

Not only is this evidence of an unexpected result that overcomes any assertion of obviousness, the fact that Uemura and Kamachi do not appreciate these significant differences establishes that the cited prior art cannot motivate a person of ordinary skill in the art to select the claimed stabilizers from a genus of hydrolysis stabilizers.

Accordingly, the Examiner has not established a *prima facie* case of obviousness because one skilled in the art would not have had a reasonable expectation from Uemura and Kamachi that a hydrolysis stabilizer falling within the claimed hydrogen distance range and requisite amount would be more successful than stabilizers outside the claimed range. Thus, Applicants respectfully submit that the rejection should be withdrawn.

As Applicants noted in their prior response, the Examiner's reliance upon U.S. Patent No. 6,577,796 ("the '796 patent") as prior art is misplaced. For art to be relied upon under 35 U.S.C. § 103(a) as the basis for an obviousness rejection, the art must first qualify as prior art under the definition of 35 U.S.C. § 102.

Applicants' application is a national phase application based on PCT/EP02/14554, filed December 19, 2002, and claims priority of EP 0113060.6, filed December 28, 2001, and U.S. Provisional Application No. 60/345,656, filed January 8, 2002. The '796 patent, which issued June 10, 2003, is also a national phase application based on PCT/EP99/07511, filed October 6, 1999. Accordingly, the '796 patent is only available as possible § 102(e) prior art.

While the '796 patent qualifies as § 102(e) prior art, it is not available as prior art for an obviousness rejection pursuant to 35 U.S.C. § 103(c). 35 U.S.C. § 103(c) states that subject matter that qualifies as prior art only under 35 U.S.C. §§ 102(e), (f), and/or (g) is disqualified as prior art against the claimed invention if that "subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Common ownership may be established by a conspicuous statement indicating that the claimed invention and a § 102(e) reference were, at the time the invention was made, commonly owned or subject to an obligation of assignment to the same person. *See* M.P.E.P. § 706.02(l)(2)(II).

With this in mind, the '796 patent is not available as prior art, because the present invention and the '796 patent were, at the time the invention was made, subject to an obligation of assignment to the same person, *i.e.*, Pirelli Cavi e Sistemi S.p.A. *See* M.P.E.P. § 706.02(l)(2)(II).

Because the '796 patent is not available as prior art in a § 103(a) rejection of the instant application, Applicants respectfully submit that the Examiner cannot rely upon it to support the pending § 103 rejection.

Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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